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| 09/221,931 | 12/28/1998 | TAKASHI TSURUO | WAKAB37.001A | 3902 |

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EXAMINER

BORIN, MICHAEL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

DATE MAILED: 07/16/2002

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/221,931

Applicant(s)
Tsuruo et al

Examiner
Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 1, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 and 17-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Continued Prosecution Application

The request filed on 5/1/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/221931 is acceptable and a CPA has been established. An action on the CPA follows.

Status of Claims

1. Claims 11, 20 are amended. Claims 22-25 are added. Claims 11, 17-25 are pending.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 17-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. The rejection is applied for the following reasons:

- A. The claims are amended (claim 11) to read on concentrations of catechin which are "higher than a concentration which can be reached by oral administration of the catechin". The claims fail to particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. The term "concentration which can be reached by oral administration" is a relative term which renders the claim indefinite. A concentration which can be reached by oral administration of the catechin is not defined either in specification or in the claims. The specification does not provide a standard for ascertaining the requisite concentrations, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.
- B. Claim 11 recite "maintaining concentration". It is not clear what concentration is meant, *in vivo*, in blood stream, around a cell, on a cell membrane, in cell cytoplasm, or in cell nucleus?
- C. Claims 11,17-21 are not clear as to whether "contacting cells" with catechins occurs *in vitro* or *in vivo*. As claim 11 now presents concentration of catechins in reference to oral administration, and in view of claims 22-25 drawn to administering to humans, the claims are interpreted as reading on *in vivo* administration.

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D. Claim 15: the phrase "concentrations including 15 μ M" is not clear. What range of concentrations is being addressed?

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 11,17-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

First, claim 11 introduces new matter as they introduce limitation "higher than a concentration which can be reached by oral administration of the catechin". Specification does not teach such limitation. Contrary, specification indicates that formulations can be either oral (such as tablets, syrups) or injectable. As to the reference made by applicant to paragraph bridging pages 5-6, said paragraph teaches a particular way of preparing a formulation, and not dosages of its administering.

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Second, claims 23-25 recite dosage of 15 μ M. Such dosage is not taught in specification as dosage for *in vivo* administration; rather it was used to demonstrate *in vitro* effect of a particular catechine, EGCG, on cell culture. There is no teaching of *in vivo* dosage expressed in μ M concentrations; rather specification teaches range of 500-2000 mg/day (p. 7) which is well within dosages described in the prior art.

4. Claims 11 and its dependent claims 17-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 11 introduces new matter as they introduce an unsupported specific negative limitation to exclude concentrations below "concentration which can be reached by oral administration of the catechin". The examiner has not found *ipsis verbis* support for this negative claim limitation in the specification nor has applicant indicated where such specification support exists (the showing addressed by applicant is drawn to *in vitro* experiments). A negative limitation must have basis in the original disclosure. Ex parte Grasselli, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). MPEP 2173.05 (I) instructs that any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under

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35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Applicant must cancel the new matter in response to this rejection.

Claim Rejections - 35 U.S.C. § 102

5. Claims 11, 17-23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over JP 910108977.

JP 910108977 teaches that catechins obtained from green tea concentrates prevented development of colon cancer. It is known in the prior art that 1) green tea is effective as a cancer preventive, 2) catechins are known to be active ingredients of green tea or green tea extracts; 3) telomerase is active in cancer cells and is dormant in normal cells. The catechins were purified from green tea to 93% purity. The preferred concentration of catechins is 0.05-0.7% (see abstract), which is equivalent to range 1.7-24 μ M (calculated using 290.3 as the molecular weight of catechin;as provided for product #9510 in Sigma catalog).

Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. In the instant case, the only method step as instantly claimed is contacting cells (ie via administration) with a

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composition comprising a catechin. It is Examiner's position that any reference teaching exposure of cells, *in vitro* or *in vivo*, to a composition comprising catechins (e.g., green tea) in its normal and usual operation would necessarily perform the method as claimed because prevention of cancer prevents telomerase activity.

Response to arguments

Applicant argues that the reference teaches administration of "much lower levels of polyphenols" than the claimed method and is limited to oral administration. Examiner disagrees. First, the preferred concentration of catechins in the reference is 0.05-0.7% (see abstract), which is equivalent to range 1.7-24 μM . Second, the instant claims are not drawn to a particular dosage, rather they recite administration in amount "higher than concentration which can be reached by oral administration", the latter has not being defined.

Applicant further argues that applicant invention is drawn to administration of dosage suitable for parenteral administration. This language does not define any concentration range, and, further, is not present in the instant claims.

Applicant attempts to correlate numerical data obtained in the reference and other publication. However, it is difficult to recalculate data obtained on different animals and under different conditions.

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Further applicant argues that the dosage range in the reference (300-600 mg/ml) is different from those used in the instant invention. However, the instant specification recites range 500-2000 mg/day, which overlaps with the range in the reference.

6. Claims 11, 17-23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C.103(a) as obvious over Fujiki et al. (Nutrition Reviews, 54(11), S67-S70, 1996) or Liao et al. (Cancer Letters, 96,239-243, 1995) or admitted prior art.

The prior art teaches that green tea is effective as a cancer preventive. More specifically, catechins, taken either as a part of tea or in a purified form, are known to be an active ingredient of tea. See Fujiki or Liao references or specification, p. 2. Under the principles of inherency, if a prior art method, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art. When the prior art method is the same as a method described in the specification, it can be assumed the method will inherently perform the claimed process. See MPEP 2112.02. In the instant case, the only method step as instantly claimed is contacting cells (ie via administration) with a composition comprising a catechin. It is Examiner's position that any reference

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teaching exposure of cells, *in vitro* or *in vivo*, to a composition comprising catechins (e.g., green tea) in its normal and usual operation would necessarily perform the method as claimed. It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed or fully envisioned by the teaching of the references cited above.

7. Claims 24,25 are rejected under 35 U.S.C. 103(a) as obvious over JP 910108977 or Fujiki et al. (Nutrition Reviews, 54(11), S67-S70, 1996) or Liao et al. (Cancer Letters, 96,239-243, 1995) alone or in view of Cheng (US 5,795,911), or Huang et al. or Child (GB 2306231).

The cited prior art teaches that green tea is effective as a cancer preventive.

It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal ways of administration of catechins because routes of administration and dosage ranges are art-recognized result-effective variables which are routinely determined and optimized in the design of all pharmaceutical applications. It would be obvious to determine all modes of administration will be operable to achieve the desired results.

Further, various ways of administration of catechins are well known in the art. See, e.g., Cheng (US 5,795,911), or Huang et al. or Child (GB 2306231).

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Conclusion.

8. No claims are allowed

9 This is a CPA of applicant's earlier Application No. 09/221931. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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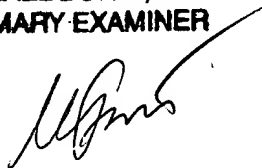
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 12, 2002

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.